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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,705	06/23/2003	Mark Yang	2498-111	5744

6449 7590 03/16/2006

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,705	YANG ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:_____.

DETAILED ACTION

Status of Objections and Rejections pending since the Office action of August 11, 2005

1. All previous rejections and objections are withdrawn.

Priority

2. Only the first page of the priority document, Taiwan patent application no. 091113636, has been received. Applicants are requested to provide the complete document.

Response to Arguments

3. Applicant's arguments filed January 11, 2006 ("Amendment") have been fully considered but they are not persuasive. Applicants assert, "The White et al. patent fails

to teach or suggest the feature of a gain adjustable amplifier which is now recited in claims 1 and 8." See page 12 of the Amendment. The Examiner respectfully disagrees. As seen in Figure 7 of White there is a switch that allows the amplifier 100 to be shunted with resistor 104. When closed, this resistor 104 will prevent saturation of the amplifier. When open, the amplifier returns to its normal gain characteristics. See col. 7:51-65. Thus, the amplifier gain may be adjusted by opening or closing the switch; that is the amplifier is gain –adjustable. Furthermore, the use of a switch to shunt another resistor across the amplifier appears to be the same means for adjusting the amplifier gain used by Applicants. See Applicants' Figures 6 and 7.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (US 5,366,609) ("White") in view of Patko et al. (US 6,153,085) ("Patko") and Ou-Yang et al. (US 2003/0204313 A10 ("Ou-Yang')

Addressing claim 1, White discloses a portable multi-functional electrochemical

biosensor system, comprising

a sample cell (18) the sample cell having a reaction zone (20) on which a substance is placed to react with a corresponding selected analyte (col. 4:33-36) and having a t least two independent electrodes (24,26) which are not connected to each other (Figure 3), wherein one of the two electrodes is a reference electrode (24), and the other is a working electrode (26), the electrodes being configured to output an electrochemical reaction signal when a detection reaction occurs (col. 5:53-58);

a pluggable information memory (30), corresponding to the sample cell (col. 5:3-18), the pluggable information memory being able to provide parameters used for analyzing the concentration of the corresponding selected analyte (claim 9; col. 5:3-18; and col. 5:66 – col. 6:13); and

a multi-functional signal analysis processor (16, Figure 3) having a microprocessor (59), a read memory (ROM) (30, Figure 3), an environmental temperature sensor (54), at least two input terminals which are connected to the sample cell and the pluggable information memory, respectively (Figure 1), wherein the microprocessor is configured to transfer the parameters from the pluggable information memory to the read memory when an electrochemical reaction occurs so that the concentration of the selected analyte can be calculated using the electrochemical reaction signal output from the sample cell, the parameters transferred to the read memory, (col. 4:56 – col. 6:13), and then output (Figures 4-6 and col. 8:36-38);

wherein the multi-functional signal analysis signal analysis processor further comprises a gain adjustable amplifier having a reverse input terminal, the reverse input

terminal being connected to the working electrode, and the processor is configured to reasonably amplify the signal of the working electrode via the gain adjustable amplifier (As seen in Figure 7 of White there is a switch that allows the amplifier 100 to be shunted with resistor 104. When closed, this resistor 104 will prevent saturation of the amplifier. When open, the amplifier returns to its normal gain characteristics. See col. 7:51-65. Thus, the amplifier gain may be adjusted by opening or closing the switch; that is the amplifier is gain –adjustable. Furthermore, the use of a switch to shunt another resistor across the amplifier appears to be the same means for adjusting the amplifier gain used by Applicants. See Applicants' Figures 6 and 7.)

White does not mention (i) providing a plurality of sample cells, (ii) providing a plurality of pluggable information memories, (iii) erasable programmable read/write memory, and (iv) the analyte concentration is calculated with cooperation of the temperature compensation established by the environmental temperature sensor.

As for a providing a plurality of sample cells and a plurality of pluggable information memories, White clearly discloses that the electrochemical biosensor system is not limited to measuring a particular analyte. See col. 3:35-65 and col. 5:27-50. Thus, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide a plurality of sample cells and a plurality of pluggable information memories to allow for a variety of analytes to be measured.

As for providing erasable programmable read/write memory, White uses read only memory (ROM), however, as shown by Patko and Ou-Yang it was known at the time to also use a variety of memories, including erasable programmable read/write

memory, in a portable electrochemical biosensor system. See in Patko the abstract and col. 11:1-41 and paragraph [0007] of Ou-Yang. Barring evidence to the contrary, such as unexpected results, in light of Patko and Ou-Yang the choice of memory, such as erasable programmable read/write memory, will depend on whether data will have to be overwritten and the energy needs of the memory device. See col. 11:1-41 in Patko and paragraphs [0004] and [0019] in Ou-Yang.

As for calculating the analyte concentrations with cooperation of the temperature compensation established by the environmental temperature sensor, although not specifically mentioned by White if not implied is obvious because the temperature sensor output is fed to the microprocessor during measurement (col. 4:65 – col. 5:2) and White discloses enzymatic reactions, which as known in the art are temperature sensitive.

Addressing claim 2, Patko and Ou-Yang both discloses EEPROM memories. See in Patko col. 11:1-23 and paragraph [0019] in Ou-Yang. Again, the choice of memory, from known memories used in electrochemical biosensors, will be based on need to change memory contents and memory energy usage.

Addressing claim 3, for the additional limitations of this claim see in White col. 5:3-18 and col. 5:66 – col. 6:13 and paragraph [0007] in Ou-Yang.

Addressing claim 4, for the additional limitations of this claim see in White col. 8:6-38.

Addressing claim 5, White discloses providing the working electrodes with a reference potential and having a signal amplified via an amplifier and a feed-back resistor, and during the detection, the electrochemical reaction signal output from the working electrode is sent to the multi-functional signal analytical processor for calculating the concentration of the selected analyte. See Figures 3 and 7. White does not mention grounding the reference electrode. However, White discloses that various voltages may be applied to the reference electrode. See col. 5:19-26. Thus, barring evidence to the contrary, such as unexpected results the voltage applied to the reference electrode, which is an intended use, is just a matter of optimizing the voltage for the measurement.

Addressing claim 7, for the additional limitations of this claim see in White col. 6:35 – col. 7:15 and note the incubation time during which the voltage to the working electrode is removed.

Addressing claim 8, White discloses a portable multi-functional electrochemical biosensor system, comprising

a sample cell (18) the sample cell having a reaction zone (20) on which a substance is placed to react with a corresponding selected analyte (col. 4:33-36) and having a t least two independent electrodes (24,26) which are not connected to each other (Figure 3), wherein one of the two electrodes is a reference electrode (24), and the other is a working electrode (26), the electrodes being configured to output an electrochemical reaction signal when a detection reaction occurs(col. 5:53-58);

a pluggable information memory (30), corresponding to the sample cell (col. 5:3-18), the pluggable information memory being able to provide parameters used for analyzing the concentration of the corresponding selected analyte (claim 9; col. 5:3-18; and col. 5:66 – col. 6:13); and

a multi-functional signal analysis processor (16, Figure 3) having a microprocessor (59), a read memory (ROM) (30, Figure 3), an environmental temperature sensor (54), and at least two input terminals which are connected to the sample cell and the pluggable information memory, respectively (Figure 1), wherein the microprocessor is configured to transfer parameters from the pluggable information to the read memory when an electrochemical reaction occurs so that the concentration of the selected analyte can be calculated using the electrochemical reaction signal output from the sample cell, the parameters transferred to the read memory, (col. 4:56 – col. 6:13), and then output (Figures 4-6 and col. 8:36-38);

wherein the multi-functional signal analysis signal analysis processor further comprises a gain adjustable amplifier, the reverse input terminal of which is connected to the working electrode, and the processor reasonably amplifies the signal of the

working electrode via the gain adjustable amplifier (As seen in Figure 7 of White there is a switch that allows the amplifier 100 to be shunted with resistor 104. When closed, this resistor 104 will prevent saturation of the amplifier. When open, the amplifier returns to its normal gain characteristics. See col. 7:51-65. Thus, the amplifier gain may be adjusted by opening or closing the switch; that is the amplifier is gain –adjustable. Furthermore, the use of a switch to shunt another resistor across the amplifier appears to be the same means for adjusting the amplifier gain used by Applicants. See Applicants' Figures 6 and 7.) to increase resolutions by the use of the parameters of the pluggable information memory, cooperating with the corresponding selected analyte (as noted above the programmable information memory provides parameters used for analyzing the sale. Such parameters "includes constants and other data required to carry out analyte-determination procedures ... Further, ROM key **30** will also contain a large number of additional variable values that control the operation of processor **59** in performing the actual analyte determination tests." See col. 5:3-18.

White does not mention (i) providing a plurality of sample cells, (ii) providing a plurality of pluggable information memories, (iii) erasable programmable read/write memory, (iv) the analyte concentration is calculated with cooperation of the temperature compensation established by the environmental temperature sensor, and (v) a status detector having two independent electrodes which are connected to a resistor with a const resistance.

As for a providing a plurality of sample cells and a plurality of pluggable information memories, White clearly discloses that the electrochemical biosensor

system is not limited to measuring a particular analyte. See col. 3:35-65 and col. 5:27-50. Thus, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide a plurality of sample cells and a plurality of pluggable information memories to allow for a variety of analytes to be measured.

As for providing erasable programmable read/write memory, White uses read only memory (ROM), however, as shown by Patko and Ou-Yang it was known at the time to also use a variety of memories, including erasable programmable read/write memory, in a portable electrochemical biosensor system. See in Patko the abstract and col. 11:1-41 and paragraph [0007] of Ou-Yang. Barring evidence to the contrary, such as unexpected results, in light of Patko and Ou-Yang the choice of memory, such as erasable programmable read/write memory, will depend on whether data will have to be overwritten and the energy needs of the memory device. See col. 11:1-41 in Patko and paragraphs [0004] and [0019] in Ou-Yang.

As for calculating the analyte concentrations with cooperation of the temperature compensation established by the environmental temperature sensor, although not specifically mentioned by White if not implied is obvious because the temperature sensor output is fed to the microprocessor during measurement (col. 4:65 – col. 5:2) and White discloses enzymatic reactions, which as known in the art are temperature sensitive.

As for a status detector having two independent electrodes which are connected to a resistor with a const resistance, Ou-Yang discloses a biosensing meter comprising a status detector, having two independent electrodes which are connected to a resistor

with a constant resistance, and to the sample cell of a multifunctional signal analysis processor, and whether the status of the multi-functional signal analysis processor is normal is based on whether the resistance of the resistor detected by the multi-functional signal analysis processor conforms to the built-in resistance of the processor. See Figure 4C and 5 and paragraph [0019]. It would have been obvious to proved a status detector as taught by Ou-Yang (including two independent electrodes in each sample cell) in the invention of White as modified by Patko and Ou-Yang because as taught by Ou-Yang this ensure correct functioning of the biosensor system and thus accurate measurement results. See paragraph [0019].

Final Rejection

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
March 10, 2006